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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/017,329	12/14/2001	Thomas D. Intini	1901-14A	8122

7590                    05/21/2003

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[REDACTED] EXAMINER

PICKETT, JOHN G

[REDACTED] ART UNIT      [REDACTED] PAPER NUMBER

3728

DATE MAILED: 05/21/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/017,329	INTINI, THOMAS D.
	Examiner Gregory Pickett	Art Unit 3728

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

#### A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 December 2001.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-6 is/are rejected.
- 7) Claim(s) 1 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 14 December 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ .                    6) Other: \_\_\_\_\_ .

## **DETAILED ACTION**

### ***Information Disclosure Statement***

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

### ***Specification***

2. The disclosure is objected to because of the following informalities: Page 5, second line of last paragraph, recites "paperboard layer 24", item 24 is previously defined as "paper layer".

Appropriate correction is required.

### ***Claim Objections***

3. Claim 1 is objected to because of the following informalities: the applicant uses inconsistent terminology by using "at least one blister pocket", "said blister pockets" and "said blister pocket" within the same claim. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said paper" in line 10. There is insufficient antecedent basis for this limitation in the claim. It is unclear as to whether the applicant is referring to a layer of paper or a reinforcing layer of paperboard material.

Claim 1 recites the limitation "said blister pockets" in line 9. There is insufficient antecedent basis for this limitation in the claim. At least one blister pocket is previously defined, allowing for the existence of a single blister pocket.

Claims 2-5 are dependent on claim 1 and are rejected for the above reasons.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.

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3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
5. Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gerner (US 3,924,747) in view of Price (US 5,339,960).

Regarding claim 1, Gerner discloses a package (10) having a blister sheet (23) with blister pockets (19); a rupturable foil (25) sealed to the back of the blister sheet (as shown, Figure 8); and a reinforcing layer (27) adhered to the blister sheet-rupturable foil combination (as shown, figures 1 and 8) with a portion (28) in registry with blister pockets (19) not adhered to the blister sheet-rupturable foil combination; and tear strips (28) formed in reinforcing layer (27) such that the reinforcing layer will delaminate (as shown, (Figure 10).

Gerner meets all limitations claimed by the applicant except for a paper layer secured to the backside of the rupturable foil.

Price discloses a package (10) with backing layers (23) and (25) and a blister pack assembly (37, Figure 6). Blister pack assembly (37) is made of blister sheet (12), rupturable foil (60) and a layer of paper (62). It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the package of Gerner with an additional paper layer as taught by Price in order to increase the force required to push the medicament through the rupturable foil layer, thereby precluding access by small children.

As to claim 2, the package of Gerner-Price discloses a plurality of blister pockets (Gerner, Figures 1-7) and a plurality of tab members (Gerner 24).

As to claim 3, the package Gerner-Price discloses a blister sheet of polyvinyl chloride (Gerner Col. 3, ll. 12-14, Price Col. 4, ll. 37-41).

As to claim 4, the package of Gerner-Price discloses a paper layer of fifteen-pound paper (Price Col 4, ll. 59-60).

As to claim 5, the package of Gerner-Price discloses single dose medicament (Gerner 18).

Regarding claim 6, the package of Gerner-Price as applied to claim 1 above discloses the claimed method by presentation.

### ***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Intini ('004) discloses a bend and peel blister package with peel panels over each individual blister chamber.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory Pickett whose telephone number is 703-305-8321. The examiner can normally be reached on Mon-Fri, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mickey Yu can be reached on 703-308-2672. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

*GP*

Gregory Pickett  
Examiner  
May 9, 2003

*Mickey Yu*

Mickey Yu  
Supervisory Patent Examiner  
Group 3700